

901 E. 233rd Street Carson, California 90745-6204 310/835-8400 Fax 310/835-6615

December 11, 2003

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street SW Washington, DC 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Leiner Health Products notifies the FDA that it has begun using the following phrase and statement:

Supports Healthy Mood and Emotional Well-Being Promotes Joint Health, Mobility and Comfort Supports Liver Health

SAM-e is a natural compound present in all living cells and is involved in many important biochemical reactions in the body.

SAM-e helps to maintain healthy mood and emotional well-being.

SAM-e helps to promote healthy cartilage formation which may enhance joint comfort and mobility.

SAM-e helps to support a healthy liver.

SAM-e has been used safely, successfully and extensively in Europe for over 20 years.

on the following product:

YourLife® SAM-e 200 mg

Very truly yours,

Leiner Health Products

William Cochran, Manager of Regulatory Affairs

975 0162 LET 135 74



Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration (continued)

The following brands also use the above statement:

Albertson's
BI-MART
BIO BALANCE®
COUNCIL LABS®
CVS®
ECKERD®
equate®
Hannaford®
HealthLine
health PRIDE
Kash n' Karry
KIRKLAND Signature™
Kroger®
Longs
MARC'S

Member's Mark

MEIJER™

Nature's Origin® NATURE'S VALLEY™ **NATURITE® NUTRA CHOICE NUTRI-BLEND** Osco® PHARMACIST FORMULA® **BODYCOLOGY™** SAFEWAY SELECT™ SaveonTM Shaw's ShopKo® Spring Valley® **TARGET® TOP CARE® TRUNATURE®** Wegmans®